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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,434	11/25/2003	Keshab D. Pant	LOMACC.003DV2	7142

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EXAMINER	
HUFF, SHEELA JITENDRA	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,434	PANT ET AL.	
	Examiner	Art Unit	
	Sheela J. Huff	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-27 and 30* is/are rejected.

7)☒ Claim(s) *28 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/25/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are cancelled.

Claims 24-30 are pending.

Priority

Applicant is requested to update the continuity data to include the patent number of 09/915031.

Information Disclosure Statement

The IDS filed 11/25/03 has been considered and an initialed copy of the PTO-1449 is enclosed.

Claim Rejections - 35 USC § 112

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terminology "the fecal sample" in claim 30 have improper antecedent basis.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an

enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials.

The specification lacks complete deposit information for the deposit of hybridoma cell line producing SP-21. It is not clear that hybridomas possessing the identical properties of the aforementioned cell line are known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Exact replication of a cell line is an unpredictable event. Although applicant has provided a written description of a method for selecting the claimed hybridoma cell lines and monoclonal antibodies, this method will not necessarily reproduce antibodies and hybridomas which are chemically and structurally identical to those claimed. It is unclear that one of skill in the art could derive a monoclonal antibody and hybridoma identical to those claimed. Undue experimentation would be required to screen all of the possible antibody and hybridoma species to obtain the claimed antibodies and hybridomas.

Because one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the claimed hybridoma, a suitable deposit for patent purposes, evidence of public availability of the claimed hybridoma or evidence of the reproducibility without undue experimentation of the claimed hybridoma, is required.

If the deposit is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record

who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If the deposit is not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-25, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pant et al Journal of Tumor Marker Oncology vol. 3 p. 1 (1988) in view of The Merck Index, Budavari, O'Neil, Smith and Heckelman, eds., p. 1357, (1989), Handbook of Experimental Immunology in Four volumes: Volume 1: Immunochemistry, Weir ed. (1987), Chapter 27 and Zuk et al US 4281061.

Pant et al discloses several immunoassays for the detection of COTA or antibodies to COTA. Specifically, in the middle of page 3, the reference discloses an

indirect ELISA in which the antibody SP-21 (which is the same one used by applicant) is coated onto the bottom of ELISA plates and then purified COTA is added as the test material.

The reference does not disclose the use of a vial containing a preservative solution or the formation of a kit.

The Merck Index discloses that sodium azide is commonly used as a preservative for laboratory reagents.

The Handbook of Experimental Immunology discloses that sodium azide (NaN3) is used in ELISA solutions (see page 2715--bottom of second column).

Pant et al also discloses the use of sodium azide in ELISA (see last two lines of p. 3).

Zuk et al. teach that reagents for an immunoassay can be provided as kits as a matter of convenience and to optimize the sensitivity of the assay in the range of interest (col 22, line 62 - col 23, line 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include the necessary reagents to perform the immunodiagnostic assay in a kit format for the convenience and economy of the user. One would have been motivated to assemble the reagents in a kit format to standardize the reagents for the optimization the assay for use in a clinical diagnostic laboratory or physician's office. Since Merck teaches that sodium azide is a preservative solution and since it is used in ELISA, it also would been obvious to use sodium azide in the buffers of the ELISAs in Pant et al with the expected benefit

of preserving the solution. It is expected that since the sodium azide is in liquid form that is contained in a container (that reads on vial).

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pant et al Journal of Tumor Marker Oncology vol. 3 p. 1 (1988) in view of Panigrahi et al J. Clinical Microbiology vol 25 p. 702 (1987), The Merck Index, Budavari, O'Neil, Smith and Heckelman, eds., p. 1357, (1989), Handbook of Experimental Immunology in Four volumes: Volume 1: Immunochemistry, Weir ed. (1987), Chapter 27 and Zuk et al US 4281061.

Pant et al discloses several immunoassays for the detection of COTA or antibodies to COTA. Specifically, in the middle of page 3, the reference discloses an indirect ELISA in which the antibody SP-21 (which is the same one used by applicant) is coated onto the bottom of ELISA plates and then purified COTA is added as the test material. Pant et al also discloses a direct ELISA assay in which the COTA is coated onto beads and then the antibody SP-21 is added.

The reference does not disclose the use of a vial containing a preservative solution, the antibody being attached to a membrane or the formation of a kit.

The Merck Index discloses that sodium azide is commonly used as a preservative for laboratory reagents.

The Handbook of Experimental Immunology discloses that sodium azide (NaN3) is used in ELISA solutions (see page 2715--bottom of second column).

Pant et al also discloses the use of sodium azide in ELISA (see last two lines of p. 3).

Zuk et al. teach that reagents for an immunoassay can be provided as kits as a matter of convenience and to optimize the sensitivity of the assay in the range of interest (col 22, line 62 - col 23, line 4).

Panigarhi et al discloses dot blot immunoassays wherein the dot blot is more effective, rapid and requires less equipment than the ELISA (see page 704-first column). The dot blot has the antigen coated onto the membrane and then labeled antibody added.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include the necessary reagents to perform the immunodiagnostic assay in a kit format for the convenience and economy of the user. One would have been motivated to assemble the reagents in a kit format to standardize the reagents for the optimization the assay for use in a clinical diagnostic laboratory or physician's office. Since Merck teaches that sodium azide is a preservative solution and since it is used in ELISA, it also would been obvious to use sodium azide in the buffers of the ELISAs in Pant et al with the expected benefit of preserving the solution. It is expected that since the sodium azide is in liquid form that is contained in a container (that reads on vial). Furthermore, one of ordinary skill in the art would have been motivated to use the dot blot assay of Pangrahi et al instead of the direct ELISA Pant et al assay because it is more effect, rapid and requires not specialized equipment. The limitation of the antibody being attached to

the membrane is met by the fact that antibody binds to the membrane through the antigen.

Allowable Subject Matter

Claims 28-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 28 and 29 are free from the art because the prior art does not teach that specified percentages.

Claim 30 is free from the art of record because the prior art does not teach COTA being present in feces.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesdays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sheela J Huff
Primary Examiner
Art Unit 1643

sjh